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BAKER & BOTTS
30 ROCKEFELLER PLAZA
NEW YORK, NY 10112

EXAMINER	
CHAKRABARTI, ARUN K	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/071,136	Applicant(s) Edward
	Examiner Arun Chakrabarti	Art Unit 1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 30, 2002*.

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-13* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims *14-22* are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 2
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☒ Other: *Detailed Action*

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-13, drawn to hybrid gene, classified in class 536, subclass 22.1.

II. Claims 14-16, drawn to method of protein expression, classified in class 435, subclass 69.1.

III. Claims 17-22, drawn to transformation of cells, classified in class 435, subclass 400.

2. The inventions are distinct, each from the other because of the following reasons: Inventions of Groups I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the gene of Group I can be used for the method of protein expression of Group I or can be used to make RNA or can be used to make antisense nucleic acid for gene therapy.

3. Inventions of Groups I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the

product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the gene of Group I can be used for the transformation of cells of Group II or can be used to make RNA and protein or can be used to make antisense nucleic acid for gene therapy.

4. Inventions of Groups II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions of method of protein expression of Group II is not disclosed as capable of use together with transformation of cells of Group III and they have different modes of operation, different functions, or different effects.

5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

6. During a telephone conversation with Michelle Lecointe on January 27, 2003 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-13. Affirmation of this election must be made by applicant in replying to this Office action. Claims 14-22 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

7. The spelling "hemagluttinin" is wrong in claim 9. It is suggested to make a correction of the spelling.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-6 and 9 are rejected under 35 U.S.C. 103(a) over Hong et al. (Proceedings of the National Academy of Sciences, (U.S.A), (May 1996), Vol. 93, pages 4948-4952) in view of Guegler et al. (U.S. Patent 6,083,727) (July 4, 2000).

Hong et al teach a hybrid gene cDNA library comprising a series of vectors (Abstract), each vector comprising a DNA molecule having at least one selectable marker sequence and a sequence encoding a hybrid protein region (Abstract and Materials and Methods Section, Construction of Recombinant Vectors Subsection), wherein the hybrid protein region comprises,

a) a regulatable DNA sequence (Chloramphenicol acetyl transferase gene in this case described in Abstract and Materials and Methods Section, Construction of Recombinant Vectors Subsection),

b) a multiple cloning site immediately 3' to the regulatable DNA sequence, wherein the multiple cloning site does not encode a translational termination sequence (Materials and Methods Section, Construction of Recombinant Vectors Subsection), and

c) a DNA sequence encoding at least one common peptide placed 3' to the multiple cloning site, wherein the common peptide (GAL4 in this case) encoding sequence does not contain a translation initiation codon, and wherein the each vector of the library additionally comprises a single cDNA molecule inserted at the multiple cloning site (Abstract and Materials and Methods Section, Construction of Recombinant Vectors Subsection).

Hong et al teach a hybrid gene, wherein each vector additionally comprises one or more origins of replication active in bacterial cells (Page 4949, Column 2, Materials and Methods Section, Interaction of GRIP1 and steroid Receptors In vitro Subsection).

Hong et al teach a hybrid gene, wherein each vector additionally comprises one or more origins of replication active in yeast cells (Page 4949, Column 2, Materials and Methods Section, Use of two-Hybrid system to isolate GRIP1 cDNA clone and study GRIP1 function in Yeast Subsection).

Hong et al teach a hybrid gene, wherein the hybrid protein region additionally comprises a sequence which encodes a transcriptional termination sequence placed immediately 3' to the DNA sequence encoding the at least one common peptide (Materials and Methods Section, Construction of Recombinant Vectors Subsection and Use of two-Hybrid system to isolate GRIP1 cDNA clone and study GRIP1 function in Yeast Subsection).

Hong et al teach a hybrid gene, wherein the regulatable DNA sequence is the rat Glucocorticoid response element and estrogen response element (Abstract and Materials and Methods Section, Construction of Recombinant Vectors Subsection).

Hong et al teach a hybrid gene, wherein the common peptide is encoded by a DNA molecule comprising sequences encoding an immunological epitope from adenoviral hemaglutinin (Materials and Methods Section, Construction of Recombinant Vectors Subsection).

Hong et al teach a hybrid gene, wherein each of the cDNA molecules is obtained from a cDNA population generated using random primers.

Guegler et al. teach a hybrid gene, wherein each of the cDNA molecules is obtained from a cDNA population generated using random primers (Abstract and Figure 1, step 3, and Experimental Section).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the hybrid gene, wherein each of the cDNA molecules is obtained from a cDNA population generated using random primers of Guegler et al in the hybrid gene library of Hong et al. since Guegler et al. states, "The subject methods find use in a variety of applications, and find particular use in the synthesis of 5' enriched cDNA libraries (Abstract, penultimate sentence) ". An ordinary practitioner would have been motivated to substitute and combine the a hybrid gene, wherein each of the cDNA molecules is obtained from a cDNA population generated using random primers of Guegler et al in the hybrid gene library of Hong et al. in order to achieve the express advantages, as noted by Guegler et al.,

of an invention which provides the methods that find use in a variety of applications, and find particular use in the synthesis of 5' enriched cDNA libraries.

10. Claim 7 is rejected under 35 U.S.C. 103(a) over Hong et al. (Proceedings of the National Academy of Sciences, (U.S.A), (May 1996), Vol. 93, pages 4948-4952) in view of Guegler et al. (U.S. Patent 6,083,727) (July 4, 2000) further in view of Reed et al. (U.S. Patent 6,492,143 B1) (December 10, 2002).

Hong et al. in view of Guegler et al teach the hybrid gene of claims 1-6 and 9 as described above including DNA molecule comprising sequences encoding all or portions of the GAL4 yeast transcriptional activator.

Hong et al. in view of Guegler et al do not teach the hybrid gene, wherein the common peptide is encoded by a DNA molecule comprising sequences encoding six successive histidine residues.

Reed et al teach the hybrid gene, wherein the common peptide is encoded by a DNA molecule comprising sequences encoding six successive histidine residues (Column 61, line 62 to Column 17, line 7).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the a hybrid gene, wherein the common peptide is encoded by a DNA molecule comprising sequences encoding six successive histidine residues of Reed et al in the hybrid gene library of Hong et al. in view of Guegler et al since Reed et al. states, "The histidine residues facilitate detection and purification (Column 16, line 67 to Column 17, line

1) ". An ordinary practitioner would have been motivated to substitute and combine the a hybrid gene, wherein the common peptide is encoded by a DNA molecule comprising sequences encoding six successive histidine residues of Reed et al in the hybrid gène library of Hong et al. in view of Guegler et al. in order to achieve the express advantages, as noted by Reed et al., of an invention which provides DNA encoding six successive histidine residues that facilitate detection and purification.

11. Claim 8 is rejected under 35 U.S.C. 103(a) over Hong et al. (Proceedings of the National Academy of Sciences, (U.S.A), (May 1996), Vol. 93, pages 4948-4952) in view of Guegler et al. (U.S. Patent 6,083,727) (July 4, 2000) further in view of Bradfield et al. (U.S. Patent 6,432,692 B1) (August 13, 2002).

Hong et al. in view of Guegler et al teach the hybrid gene of claims 1-6 and 9 as described above including DNA molecule comprising sequences encoding all or portions of the GAL4 yeast transcriptional activator.

Hong et al. in view of Guegler et al do not teach the hybrid gene, wherein the common peptide is encoded by a DNA molecule comprising sequences encoding all or portions of the GAL4 yeast transcriptional activator and a nuclear localization sequences from the SV40 virus.

Bradfield et al. teach the hybrid gene, wherein the common peptide is encoded by a DNA molecule comprising sequences encoding all or portions of the GAL4 yeast transcriptional activator and a nuclear localization sequences from the SV40 virus. (Column 11, lines 4-11).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the a hybrid gene, wherein the common peptide is encoded by a DNA molecule comprising sequences encoding all or portions of the GAL4 yeast transcriptional activator and a nuclear localization sequences from the SV40 virus of Bradfield et al in the hybrid gene library of Hong et al. in view of Guegler et al. since Bradfield et al. states, "The psg42 vector contains the amino terminal 147 amino acids of the yeast Gal4 protein under the control of a SV40 promoter, followed by a multiple cloning site that allows in-frame cloning of sequences derived from a second cDNA (Column 11, lines 7-11)". An ordinary practitioner would have been motivated to substitute and combine the a hybrid gene, wherein the common peptide is encoded by a DNA molecule comprising sequences encoding all or portions of the GAL4 yeast transcriptional activator and a nuclear localization sequences from the SV40 virus of Bradfield et al in the hybrid gene library of Hong et al. in view of Guegler et al. in order to achieve the express advantages, as noted by Bradfield et al., of an invention which provides a vector containing the amino-terminal 147 amino acids of the yeast Gal4 protein under the control of a SV40 promoter, followed by a multiple cloning site that allows in-frame cloning of sequences derived from a second cDNA.

12. Claim 10 is rejected under 35 U.S.C. 103(a) over Hong et al. (Proceedings of the National Academy of Sciences, (U.S.A), (May 1996), Vol. 93, pages 4948-4952) in view of Guegler et al. (U.S. Patent 6,083,727) (July 4, 2000) further in view of Oberto et al. (U.S. Patent 5,336,609) (August 9, 1994).

Hong et al. in view of Guegler et al teach the hybrid gene of claims 1-6 and 9 as described above including DNA molecule comprising sequences encoding all or portions of the GAL4 yeast transcriptional activator.

Hong et al. in view of Guegler et al do not teach the hybrid gene, wherein at least one yeast origin of replication is derived from the natural 2-micron yeast plasmid.

Oberto et al teach the hybrid gene, wherein at least one yeast origin of replication is derived from the natural 2-micron yeast plasmid (Example 2, Column 7, line 59 to Column 8, line 20 and Figure 6).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the a hybrid gene, wherein at least one yeast origin of replication is derived from the natural 2-micron yeast plasmid of Oberto et al. in the hybrid gene library of Hong et al. in view of Guegler et al. since Oberto et al. states, "In contrast, the natural 2-micron plasmid is stably inherited. It is indeed known that plasmids constructed in such a way that they contain the entire 2-micron plasmid are more stable than those of the pJDB207-type. Such plasmids are therefore more useful for long term growth as, for example, in industrial fermentations (Column 8, lines 1-10) ". An ordinary practitioner would have been motivated to substitute and combine the a hybrid gene, wherein at least one yeast origin of replication is derived from the natural 2-micron yeast plasmid of Oberto et al. in the hybrid gene library of Hong et al. in view of Guegler et al. in order to achieve the express advantages, as noted by Oberto et al., of the natural 2-micron plasmid which is stably inherited and which makes

the plasmids more stable than those of the pJDB207-type, rendering them more useful for long term growth as, for example, in industrial fermentations.

13. Claims 11-12 are rejected under 35 U.S.C. 103(a) over Hong et al. (Proceedings of the National Academy of Sciences, (U.S.A), (May 1996), Vol. 93, pages 4948-4952) in view of Guegler et al. (U.S. Patent 6,083,727) (July 4, 2000) further in view of Miyanohara et al. (U.S. Patent 5,707,862) (January 13, 1998).

Hong et al. in view of Guegler et al teach the hybrid gene of claims 1-6 and 9 as described above including DNA molecule comprising sequences encoding all or portions of the GAL4 yeast transcriptional activator.

Hong et al. in view of Guegler et al do not teach the hybrid gene, wherein the selectable marker sequences are selected from bacterial ampicillin and kanamycin resistance genes.

Miyanohara et al teach the hybrid gene, wherein the selectable marker sequences are selected from bacterial ampicillin and kanamycin resistance genes (Column 2, lines 18-26 and Example, Column 4, lines 62-66 and Column 6, lines 58-63).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the hybrid gene, wherein the selectable marker sequences are selected from bacterial ampicillin and kanamycin resistance genes. of Miyanohara et al. in the hybrid gene library of Hong et al. in view of Guegler et al. since Miyanohara et al. states, "The selective marker includes, for example, an ampicillin-resistant gene, a kanamycin-resistant gene, tetracycline-resistant gene, chloramphenicol-resistant gene, or the like, which may be used

alone or in combination of two or more thereof (Column 2, lines 21-26)". An ordinary practitioner would have been motivated to substitute and combine the hybrid gene, wherein the selectable marker sequences are selected from bacterial ampicillin and kanamycin resistance genes. of Miyanohara et al. in the hybrid gene library of Hong et al. in view of Guegler et al.. in order to achieve the express advantages, as noted by Miyanohara et al., of an invention which provides selective marker including, an ampicillin-resistant gene, a kanamycin-resistant gene, or the like, which may be used alone or in combination of two or more thereof.

14. Claim 13 is rejected under 35 U.S.C. 103(a) over Hong et al. (Proceedings of the National Academy of Sciences, (U.S.A), (May 1996), Vol. 93, pages 4948-4952) in view of Guegler et al. (U.S. Patent 6,083,727) (July 4, 2000) further in view of Passmore et al. (U.S. Patent 6,277,639 B1) (August 21, 2001).

Hong et al. in view of Guegler et al teach the hybrid gene of claims 1-6 and 9 as described above including DNA molecule comprising sequences encoding all or portions of the GAL4 yeast transcriptional activator.

Hong et al. in view of Guegler et al do not teach the hybrid gene, wherein the transcriptional termination sequence is derived from the yeast ADH1 gene.

Passmore et al teach the hybrid gene, wherein the transcriptional termination sequence is derived from the yeast ADH1 gene (Column 27, lines 55-56 and Figure 4).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute and combine the a hybrid gene, wherein the transcriptional

termination sequence is derived from the yeast ADH1 gene of Passmore et al in the hybrid gene library of Hong et al. in view of Guegler et al. since Passmore et al. states, "In conclusion, multifragment in vivo cloning provides an easy way to map mutations. It facilitates the physical separation of multiple changes in a target sequence (Column 27, line 14-16) ". An ordinary practitioner would have been motivated to substitute and combine the a hybrid gene, wherein the transcriptional termination sequence is derived from the yeast ADH1 gene of Passmore et al in the hybrid gene library of Hong et al. in view of Guegler et al. in order to achieve the express advantages, as noted by Passmore et al., of an invention which provides an easy way to map mutations and facilitates the physical separation of multiple changes in a target sequence

Conclusion

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D. whose telephone number is (703) 306-5818.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703) 308-1119.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Chantae Dessau whose telephone number is (703) 605-1237.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission via the P.T.O. Fax Center located in Crystal Mall 1. The CM1 Fax Center numbers for Technology Center 1600 are either (703) 305-3014 or (703) 308-4242. Please note

that the faxing of such papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989).

Arun Chakrabarti
Patent Examiner
Art Unit 1634

March 25, 2003